

TRAINING AND CAREER DEVELOPMENT IN BIOPSYCHOSOCIAL RHEUMATIC,
MUSCULOSKELETAL, AND SKIN DISEASES RESEARCH

RELEASE DATE: May 6, 2003

RFA: AR-03-010

National Institute of Arthritis and Musculoskeletal and Skin Diseases
(NIAMS)
(<http://www.niams.nih.gov>)

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LETTER OF INTENT RECEIPT DATE: August 24, 2003

APPLICATION RECEIPT DATE: September 24, 2003

THIS RFA CONTAINS THE FOLLOWING INFORMATION

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PURPOSE OF THIS RFA

Biopsychosocial perspectives and approaches to research can contribute to our understanding of the etiology, course, and outcomes of rheumatic, musculoskeletal, and skin diseases, but behavioral research in these disorders has been relatively limited. To increase integration of behavioral and biopsychosocial approaches into rheumatic, musculoskeletal, and skin diseases research, the NIAMS has identified a fundamental need to foster interdisciplinary training of scientists with interests in these diseases. Behavioral scientists who wish to pursue biobehavioral research in rheumatic, musculoskeletal, or skin diseases may require additional training in the biomedical and clinical aspects of these diseases; biomedical scientists may require training in behavioral theory and methods. This announcement is intended to attract promising behavioral researchers to the study of rheumatic, musculoskeletal, and skin diseases, and to encourage biomedical researchers to adopt a biopsychosocial approach to research, with the ultimate goal of enhancing the quality and quantity of interdisciplinary biobehavioral research in these diseases. With this RFA, the NIAMS is requesting applications for fellowships (postdoctoral

and senior), Mentored Research Scientist Development Awards, Mentored Clinical Scientist Development Awards, and Mentored Career Transition Awards in behavioral research in rheumatic, musculoskeletal, and skin diseases.

RESEARCH OBJECTIVES

In the biopsychosocial model, health and illness are conceptualized as products of a variety of factors including biological variables (e.g., genetic predisposition, exposure to pathogens), psychological factors (e.g., behaviors, beliefs, attitudes, emotions), and social conditions (e.g., social support, cultural influences). Perturbations occurring at any level in the hierarchical biopsychosocial system, from the molecular to the societal, exert effects on other levels. Thus, understanding the etiology, pathogenesis, and outcomes of disease, and developing effective strategies for prevention and treatment, require investigation in multiple separate domains and at multiple separate levels of analysis, but also necessitate collaborative research efforts that integrate approaches and perspectives from multiple disciplines. This need is particularly strong in chronic conditions, such as rheumatic, musculoskeletal, and skin diseases, whose etiology and course are often poorly understood, and which can cause long-term pain, disability, and distress.

Biomedical approaches to research in the rheumatic, musculoskeletal, and skin diseases continue to yield important discoveries regarding genetic, immunologic, and other biological factors in these diseases. Behavioral and social science research is contributing important information and approaches to managing the distressing symptoms of these disorders. However, research integrating behavioral, basic biomedical, and clinical perspectives has been extremely limited. Among the obstacles delaying the development of biopsychosocial research in these diseases are professional cultures and demands that limit interaction among basic biomedical, behavioral, and clinical scientists. In the long-term interest of promoting a biopsychosocial research agenda, the NIAMS wishes to facilitate interdisciplinary collaboration among scientists with interests in, or relevant to, these diseases by supporting research training opportunities for scientists wishing to conduct biopsychosocial research in rheumatic, musculoskeletal, or skin diseases. Applications must include both research and training/mentoring components.

RESEARCH. Research proposed must examine the contributions of behavioral or psychosocial factors to disease risk, course, or outcomes or examine the interaction of behavioral/psychosocial factors with physiological functioning relevant to disease susceptibility, course, or outcomes. Examples of research in rheumatic, musculoskeletal, or skin disease that could support the overall goals of this RFA include, but are not limited to:

- o Investigation of the role of stress, coping, and related psychosocial factors in influencing disease course and presentation (e.g., symptom flares in lupus and arthritis or eczema and psoriasis; the influence of stress management techniques and interventions on illness; potential mechanisms of stress-illness effects)
- o Studies incorporating biopsychosocial approaches to understanding sex, ethnic, and/or socioeconomic differences in clinical disease, symptom perception and management, and interactions with the health care system
- o Studies examining fatigue - epidemiological issues, potential mechanisms, approaches to prevention and treatment
- o Investigation of various aspects of chronic disease in children, including pain, psychosocial adjustment, physical functioning, and intervention approaches
- o Investigation of biopsychosocial approaches to understanding chronic pain and pain management; studies on tailoring research and intervention techniques based on individual characteristics
- o Investigation of the psychosocial burden of these diseases
- o Investigation of cognition and cognitive dysfunction
- o Studies examining relationships among cognition, mood disturbance, and disease activity
- o Investigation of sleep disturbances and their relationship to disease process, symptoms, and disability
- o Investigation of CNS-endocrine-immune interactions
- o Investigation of the interaction of genetic, behavioral, and social factors
- o Experimental studies in animal models to elucidate biobehavioral mechanisms

TRAINING AND CAREER DEVELOPMENT. The purpose of this RFA is to provide behavioral, social, and biomedical scientists with training and research experience that will enable them to pursue a career in biopsychosocial research in rheumatic, musculoskeletal, and skin diseases. Applications must have a training or mentoring plan that details the proposed didactic training and/or mentoring experiences. The applicant must propose a mentoring committee consisting of two or more faculty members, at least one of whom is a behavioral scientist and at least one of whom is a physician or basic scientist actively engaged in research on rheumatic, musculoskeletal, or skin disease. The committee and applicant should work together to develop a proposal indicating how the committee will work to promote, advance, and enhance the applicant's research career. The application should indicate in what courses, activities (e.g., journal clubs, meetings), and research experiences the applicant will engage to learn about the clinical,

biomedical, and behavioral issues in the disease(s) of interest. Mentors with NIAMS-funded grants may apply for a non-competing administrative supplement of up to \$10,000 in direct costs to support research supplemental to the mentor's grant in which the applicant may be engaged as part of his/her training.

MECHANISMS OF SUPPORT

This RFA will use NIH F32, F33, K01, K08, K22, and K23 award mechanisms. As an applicant, you and your mentoring committee will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. The anticipated award date is March 15, 2004. Awards are not renewable.

FELLOWSHIP AWARDS. The National Institutes of Health (NIH) awards NRSA individual postdoctoral fellowships (F32) to promising applicants with the potential to become productive, independent investigators in fields related to the mission of the NIH constituent institutes and centers, and NRSA senior fellowships (F33) to experienced scientists who wish to make major changes in the direction of their research careers or who wish to broaden their scientific background by acquiring new research capabilities. For full descriptions of the congressionally mandated NRSA

fellowship programs, please see PA 00-104 at

<http://www.grants.nih.gov/grants/guide/pa-files/pa-03-067.html> (F32)

and

PA 00-131 at

http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_131.pdf (F33).

Fellowship awardees are required to pursue their research training on a full-time basis, devoting at least 40 hours per week to the training program. Research clinicians must devote full-time to their proposed research training and must restrict clinical duties within their full-time research training experience to activities that are directly related to the research training experience. An NRSA fellowship (F32 or F33) may not be used to support studies leading to the M.D., D.O., D.D.S., D.V.M., or other similar health-professional degrees. Neither may these awards be used to support the clinical years of residency training.

Senior fellowship support may be requested for a period of up to 2 years; postdoctoral fellowship support may be requested for up to 3 years. No fellow may receive more than 3 years of aggregate NRSA support

at the postdoctoral level, including any combination of support from institutional and individual awards. Exceptions to the three-year limit require a waiver from the NIH awarding component. Individuals seeking a waiver should consult with relevant NIH staff. If the need for a waiver is anticipated, the application should include a justification for training beyond three years of aggregate NRSA support.

MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARDS. Mentored Research Scientist Development Awards (K01) provide research scientists with an additional period of sponsored research experience as a way to gain expertise in a research area new to the applicant or in an area that would demonstrably enhance the applicant's scientific career. These awards provide support for an intensive, supervised career development

experience in behavioral rheumatic, musculoskeletal, or skin diseases leading to research independence. Candidates for this award normally must have a research or clinical doctorate in psychology or a related behavioral science, and postdoctoral research experience at the time of application. In addition, the candidate must be able to demonstrate the need for a three, four, or five-year period of additional supervised research as well as the capacity and/or the potential for highly productive independent research. The proposed career development experience must be in a research area new to the applicant and/or one in

which an additional supervised research application is in a fundamentally new field of study or there has been a significant hiatus in the applicant's research career because of family or other personal obligations. Full eligibility criteria and application requirements for the K01 are detailed in PA-00-019 at

http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_019.pdf.

MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD. Mentored Clinical Scientist Development Awards (K08) support the development of outstanding clinician research scientists. This mechanism provides specialized study for individuals with a health professional doctoral degree committed to a career in laboratory or field-based research. Candidates must have the potential to develop into independent investigators. The K08 supports a three, four, or five year period of supervised research experience that may integrate didactic studies with laboratory or clinically based research. The proposed research must have

intrinsic research importance as well as serving as a suitable vehicle for learning the methodology, theories, and conceptualizations necessary

for a well-trained independent researcher. Full eligibility criteria and

application requirements for the K08 are detailed in PA-00-003 at

http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_003.pdf.

MENTORED CAREER TRANSITION AWARDS. Mentored Career Transition Awards (K22) provide support for outstanding early-career investigators to obtain a research training experience in the NIAMS Intramural Research Program and to facilitate their successful transition to an extramural environment as independent researchers. These awards provide support for

two to three years of research training in an NIAMS intramural laboratory, followed by two to three years of support for an independent

research project in an extramural institution. The combined duration cannot exceed five years. It is anticipated that awardees will subsequently obtain research project grants such as the R01 to support the continuation of their work. The NIAMS intramural research environment provides a rich and unique opportunity for the training of postdoctoral fellows and beginning investigators. Full eligibility criteria and application requirements for the K22 are detailed in PAR-02-056

at http://www.niams.nih.gov/rtac/funding/grants/pa/par_02_056.pdf.

MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS. Mentored Patient-Oriented Research Career Development Awards (K23) support supervised study and research for clinically trained professionals who

have the potential to develop into productive clinical investigators focusing on patient-oriented research. Candidates must have completed their clinical training prior to receiving an award. For the purposes of

this award, patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials, and 4) the development of new technologies. Full eligibility criteria and application requirements for the K23 are detailed in PA-00-004

at http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_004.pdf.

This RFA uses just-in-time concepts.

FUNDS AVAILABLE

The NIAMS intends to commit approximately \$500,000 total costs in FY 2004 to fund 2 to 5 new awards in response to this RFA. An applicant may request a project period of up to 2 years for the senior fellowship, up to 3 years for the postdoctoral fellowship, and up to 5 years for the career awards. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NIAMS provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

You may submit an application if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic
- o Faith-based or community-based organizations

Foreign institutions are not eligible to apply.

INDIVIDUALS ELIGIBLE TO BECOME FELLOWS AND CAREER AWARDEES

Citizenship. By the time of award, candidates must be citizens or non-citizen nationals of the United States, or must have been lawfully admitted to the United States for Permanent Residence (i.e., possess a currently valid Alien Registration Receipt Card I-551, or other legal verification of such status). Non-citizen nationals are generally persons born in outlying possessions of the United States (i.e., American Samoa and Swains Island). Individuals on temporary or student visas are not eligible.

Degree Requirements. Before a fellowship or career award can be

activated, the individual must have received a Ph.D., Sc.D., Dr. P.H., D.S.W., Psy.D. M.D. or equivalent doctoral degree from an accredited domestic or foreign institution. Certification by an authorized official

of the degree-granting institution that all degree requirements have been met is also acceptable. Applicants for the Senior NRSA Fellowship must be at least seven years beyond the qualifying doctoral degree and must have had at least 7 years of relevant research or professional experience. The applicant will have established an independent research career and now be seeking support for retraining or additional career development.

Sponsor. Before submitting an application, the applicant must identify a

sponsoring institution and a committee of at least two individuals who will serve as sponsors (also called mentors or supervisors) and will supervise the training and research experience.

At least one of the applicant's sponsors should be an active investigator in a health-related area of behavioral or social science research, and at least one sponsor should be an active clinical or basic

biomedical investigator in rheumatic, musculoskeletal, or skin diseases research. The sponsors will directly supervise the candidate's research.

The sponsor must document the availability of research support and facilities for high-quality research training. In most cases, the F32 and F33 support research-training experiences in new settings in order to maximize the acquisition of new skills and knowledge. However, in unusual circumstances, applicants may propose postdoctoral training experiences at their doctorate institution or at the institution where they have been training for more than a year. In such cases, the applicant must carefully document the opportunities for new research training experiences specifically designed to broaden their scientific background.

ALLOWABLE COSTS

For details regarding allowable costs for fellowships, please refer to PA 00-104 at <http://www.grants.nih.gov/grants/guide/pa-files/pa-03-067.html> (F32) or PA 00-131 at http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_131.pdf (F33).

For full details of allowable costs for the career awards, consult http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_019.pdf (K01), http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_003.pdf (K08), http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_004.pdf (K23) or http://www.niams.nih.gov/rtac/funding/grants/pa/par_02_056.pdf (K22).

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

- o Direct your questions about scientific/research issues to:

Deborah N. Ader, Ph.D.
Director, Behavioral and Prevention Research Program
NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5032
Fax: (301) 480-1284
Email: aderd@mail.nih.gov

o Direct your questions about peer review issues to:

Teresa Nesbitt, D.V.M., Ph.D.
Acting Chief, Review Branch
NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-4953
Fax: (301) 480-4543
Email: NesbittT@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Melinda Nelson
Grants Management Officer
NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-3535
Fax: (301) 480-5450
Email: nelsonm@mail.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

- o Descriptive title of the proposed research
- o Name, address, and telephone number of the Principal Investigator
- o Names of other key personnel
- o Participating institutions
- o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Deborah N. Ader, Ph.D.
Director, Behavioral and Prevention Research Program

NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5032
Fax: (301) 480-1284
Email: aderd@mail.nih.gov

SUBMITTING AN APPLICATION - FELLOWSHIPS

Applications must be prepared using the PHS 416-1 application forms and instructions for Individual National Research Service Award Fellowships (REV. 6/02). The PHS 416-1 is available at <http://grants.nih.gov/grants/forms.htm> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATIONS MUST INCLUDE AT LEAST THREE SEALED LETTERS OF REFERENCE. APPLICATIONS WITHOUT AT LEAST THREE LETTERS OF REFERENCE WILL BE RETURNED OR DELAYED IN REVIEW. If the applicant has been lawfully admitted to the United States for permanent residence, the appropriate item should be checked on the Face Page of the application. Applicants who have applied for and have not yet been granted admission as a permanent resident should check the Permanent Resident block on the Face Page of the application, and also write in the word "pending." A notarized statement documenting legal admission for permanent residence must be submitted prior to the issuance of an award.

The applicant must identify RFA-AR-03-010 in Item 3 of the PHS 416-1.

Concurrent Applications. An individual may not have more than one individual NRSA fellowship or comparable application pending review or award at the NIH or other DHHS agencies at the same time.

Instructions in the Responsible Conduct of Research.

Applications must include the candidate's plans for obtaining instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction. The amount and nature of faculty participation must be described. No award will be made if an application lacks this component.

INCOMPLETE APPLICATIONS WILL NOT BE REVIEWED

Submit a signed, typewritten original of the application (including the Checklist, Personal Data form, AT LEAST THREE SEALED REFERENCE LETTERS, and all other required materials) and one (1) exact, clear, single-sided photocopy of the signed application, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

In addition, send one copy of the application to:

Teresa Nesbitt, D.V.M., Ph.D.
Acting Chief, Review Branch
NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-4953
Fax: (301) 480-4543
Email: NesbittT@mail.nih.gov

All applications submitted to the Center for Scientific Review must come via United States Postal Service or a recognized delivery/courier service. Individuals may not personally deliver packages to the building on Rockledge Drive. For further information please see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html>

SUBMITTING AN APPLICATION - CAREER AWARDS

Career award applicants must submit applications using grant application form PHS 398 (rev. 5/01). The applicant must identify RFA-AR-03-010 in Item 2 of the PHS 398. The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html#updates>. Instructions regarding the structure and content of applications for the K01 award are detailed in PA-00-019, which is available at http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_019.pdf. Instructions regarding the structure and content of applications for the K08 award are detailed in PA-00-003, which is available at http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_003.pdf. Instructions regarding the structure and content of applications for the K23 award are detailed in PA-00-004, which is available at http://www.niams.nih.gov/rtac/funding/grants/pa/pa_00_004.pdf. Instructions regarding the structure and content of applications for the K22 award are detailed in PA-00-003, which is available at PAR-02-056 at http://www.niams.nih.gov/rtac/funding/grants/pa/par_02_056.pdf.

INCOMPLETE APPLICATIONS WILL NOT BE REVIEWED

Submit a signed, typewritten original of the application (including the Checklist, Personal Data form, AT LEAST THREE SEALED REFERENCE LETTERS, and all other required materials) and three (3) exact, clear, single-sided photocopies of the signed application, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

In addition, send two (2) copies of the application to:

Teresa Nesbitt, D.V.M., Ph.D.
Acting Chief, Review Branch
NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-4953
Fax: (301) 480-4543
Email: NesbittT@mail.nih.gov

All applications submitted to the Center for Scientific Review must come via United States Postal Service or a recognized delivery/courier service. Individuals may not personally deliver packages to the building on Rockledge Drive. For further information please see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html>

SUPPLEMENTAL INSTRUCTIONS

The requirement for a mentoring committee is unique and is intended to foster interdisciplinary collaboration and training, which is a primary goal of this RFA. The application must explain the committee composition, discuss how the expertise of the sponsors complement each other, provide biosketches for each committee member, and indicate the ability and willingness of the committee members jointly to supervise the fellow or career awardee.

The application must clearly propose research that is biobehavioral, biopsychosocial, other otherwise interdisciplinary in a way that integrates behavioral and biomedical issues, concepts, and/or approaches. Research that is limited to only one level of analysis (e.g., purely biochemical or purely behavioral) will not be considered responsive to this RFA.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

APPLICATION PROCESSING: Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending

application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes. While the investigator may still benefit from the previous review, the RFA application is not to state explicitly how.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by NIAMS.

Incomplete applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Receive a written critique
- o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
- o Receive a second level review by the NIAMS National Advisory Council.

REVIEW CRITERIA

The review criteria focus on four main components:

- o Candidate: An assessment of the candidate's previous academic and research performance and the potential to become an important contributor to behavioral or biobehavioral research in rheumatic, musculoskeletal, or skin diseases.
- o Sponsors and Training Environment: An assessment of the quality of the training environment and the qualifications of the sponsoring committee as mentors for the proposed research training experience.
- o Research Proposal: The merit of the scientific proposal and its relationship to the candidate's career plans.
- o Training/Career Potential: An assessment of the value of the proposed fellowship or career award experience as it relates to the candidate's needs in preparation for a career as an independent researcher, or for enhancing or changing the focus of the applicant's research career.

Notification. Shortly after the Scientific Review Group (SRG) meeting, each applicant will be notified by mail of the SRG recommendation and the name and phone number of the Institute program official responsible for the application. When the program official representing the Institute receives the written summary of the review, prepared by the Scientific Review Administrator (SRA) after the review meeting, a copy will be forwarded to the applicant.

Following the second-level review, the program official will notify each applicant of the final disposition of the application. Any questions on SRG recommendations and funding possibilities should be directed to the appropriate Institute program official, not the Scientific Review Administrator of the SRG. The program official to contact is:

Deborah N. Ader, Ph.D.
Director, Behavioral and Prevention Research Program
NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5032
Fax: (301) 480-1284
Email: aderd@mail.nih.gov

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: August 24, 2003
Application Receipt Date: September 24, 2003
Peer Review Date: January, 2004
Council Review: May, 2004
Earliest Anticipated Start Date: July 1, 2004

AWARD CRITERIA

NIH staff use the following criteria in making awards: (1) eligibility of the applicant; (2) the SRG recommendation of the overall merit of the application; (3) the relevance of the application to the Institute's research training priorities and program balance; and (4) the availability of funds.

Fellowship Activation. No funds may be disbursed until the fellow has started training under the award and an Activation Notice (PHS 416-5) and (when appropriate) a Payback Agreement (PHS 6031) has been submitted to the NIH. An awardee has up to 6 months from the issue date on the award notice to activate the award. Under unusual circumstances, an NIH institute may grant an extension of the activation period upon receipt of a specific request from the fellow.

REQUIRED FEDERAL CITATIONS

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide

for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public

archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

AUTHORITY AND REGULATIONS: NRSA awards are made under the authority of Section 487 of the Public Health Service Act as amended (42 USC 288), and Title 42 of the Code of Federal Regulations, Part 66. The following Catalog of Federal Domestic Assistance numbers are applicable to these awards: 93.121, 93.172, 93.173, 93.272, 93.278, 93.282, 93.306, 93.361, 93.398, 93.821, 93.837-93.839, 93.846-93.849, 93.853-93.856, 93.859, 93.862-93.867, 93.880, 93.894, and 93.929.

This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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